REMARKS

This paper is responsive to the final Office Action dated August 18, 2009. Claims 1, 2, 4-6, and 8-21 and 29 were presented for examination. Claims 22-28 have previously been withdrawn from consideration based upon a restriction requirement.

Section 112 rejections:

Claims 4 and 5 were rejected under 35 USC 112, 2nd paragraph, as being indefinite. In the Office Action the Examiner pointed out that claim 1 had previously been amended to specify that the inner tube has a substantially uniform "inner" diameter, and that dependent claims 4 and 5 should be amended in like fashion to maintain consistency of the claims. Accordingly, claims 4 and 5 have been amended to clarify that the "inner" diameter is referenced by the claims.

Although these amendments are made after final rejection, Applicants respectfully request entry of the amendments as they are essentially a housekeeping matter, and will not require additional searching or consideration. Applicants thank the Examiner for pointing out this inconsistency in the claims.

Section 103(a) rejections:

Claims 1-2, 4-6, 8-15, and 20-21.

Claims 1-2, 4-6, 8-15, and 20-21 were rejected under 35 USC 103(a) as being unpatentable over Parker (US 5,700,253)("Parker '253") in view of Lepulu et al (US 6,533,770)("Lepulu") in further view of Parker (US 5,769,830)("Parker '830").

The present application is directed to a large diameter introducer sheath of a type that may be used for percutaneous delivery of a contained and implantable medical device into the vasculature of a patient. The sheath includes a coil reinforcement which is fitted about a lubricious inner tube having a

substantially uniform inner diameter of from 16 to 30 French. The sheath further includes an outer tube positioned around the coil and the inner tube, and connected to the inner tube through spacings between respective coil turns. The outer tube has a Shore D durometer of about 30 to 60. A polymeric radiopaque marker tube may be positioned at the distal end of the sheath for radiographic visualization. A side port may be provided, e.g., for the infusion of contrast media.

Sheaths having inner diameters in the range of 16 to 30 are typically referred to as large diameter sheaths. Frequently, an important property of such sheaths is that they have sufficient flexibility so that the large diameter sheath can navigate tortuous pathways encountered in the vascular system. This is accomplished in the present large diameter sheath by providing the outer tube having a Shore D durometer of about 30 to 60. To the contrary, small diameter sheaths (about 5 to 12 French), generally include an outer tube having a Shore D durometer higher than this. Such high durometer materials provide favorable kink resistance to small diameter sheaths, and also provide sufficient strength to enable the sheath to be guided through small diameter pathways in the vasculature. However, using this same high durometer material with a larger diameter sheath may still result in a sheath that is kink resistant, but one that is more difficult to bend in actual practice when compared to smaller size sheaths. In some applications, this lack of flexibility may preclude use of the large diameter sheath altogether, or at a minimum, add a degree of difficulty and uncertainty to the procedure that would not be present if a more flexible sheath was used.

This problem is addressed in the present application by providing a large diameter sheath that has a lower durometer outer tube, when compared to the outer tube material commonly used in small diameter sheaths. As a result, the large diameter sheaths are capable of bending more easily when inserted into the vasculature, thereby permitting use of the sheath in instances when such use was previously not possible, or possible only when such use was accompanied with an added degree of difficulty and uncertainty.

In the Office Action the Examiner acknowledged that the primary Parker '253 reference does not disclose the inner sheath diameter, the side port, the Shore D hardness, and the radiopaque densities, all as claimed in at least some of the present claims. The secondary Lepulu reference was cited for teaching a device having an inner diameter of 16-29 French, and a side port located in the sheath wall. The tertiary Parker '830 reference was cited for teaching a sheath having a Shore D hardness of 50-65 (inner tube), and a radiopaque marker with varied weight percent fillers.

The present claims specify a beneficial relationship between inner sheath diameter and outer tube durometer for large diameter sheaths. Thus, as claimed in claim 1, the large diameter sheath has an inner diameter of from 16-30 French and a durometer of the outer tube of about Shore D 30 to 60. The text of the cited Parker patents discusses small diameter sheaths. As stated above, small diameter sheaths typically have an inner diameter of about 5 to 12 French, and an outer layer having a high Shore D durometer between about 60 and 80. However, teachings that discuss the features of small diameter sheaths may not adequately address certain problems that can be encountered with large diameter sheaths, as described above. Thus, although the Parker patents discuss features of small diameter sheaths, these references would be of only limited assistance to a skilled artisan investigating bendability issues encountered upon the use of large diameter sheaths, such as the sheaths claimed herein. These references they do not teach or suggest a solution to such problems, not do they even acknowledge the existence of such problems.

The Lepulu reference teaches a cannula for use in cardiopulmonary bypass surgery. The Examiner has specifically cited the embodiment depicted in Fig. 22 as the basis for use of the citation in the present rejection. The cannula disclosed therein has an inner diameter of 16-29 French. Structurally, this cannula is much different than the large diameter introducer sheath as claimed herein. The cannula has alternating reinforced sections and nonreinforced sections, wherein the nonreinforced sections have openings communicating with the lumen of the cannula. The nonreinforced sections are plain tubing and the

alternating reinforced sections may be formed by helically winding a coated elongate member around a mandrel.

As with the Parker references, Lepulu also does not teach or suggest the beneficial relationship between inner sheath diameter and outer tube durometer as claimed in claim 1. Lepulu does not deal with durometer issues regarding an outer sheath layer as described above, and in fact, does not even recite a durometer range of the outer portion of the sheath. The skilled artisan would receive little guidance from Lepulu when dealing with the problem of passing a large diameter multi-layer sheath, such as claimed herein, through a tortuous pathway within, e.g., the vascular system of a patient.

Applicants herein have uniquely combined disparate features in a manner to provide a multi-layer sheath that has a large diameter, and yet is capable of readily navigating tortuous pathways encountered in the vascular system, e.g., for percutaneous delivery of an implantable medical device. None of the cited references, either individually or in combination, teaches a sheath that combines these beneficial features.

Based upon the foregoing, Applicant submits that the subject matter of claim 1 is not obvious in view of the cited prior art. Therefore, reconsideration of the rejections is respectfully requested. In addition, the dependent claims to claim 1 as referenced in the heading above are even further removed from the teachings of the cited references. Additional reasons that these dependent claims are not obvious in view of the cited combination have been provided in detail in Applicants' previous response, and therefore, need not be repeated in this paper.

Claims 16-19 and 29.

Claims 16-19 and 29 were rejected under 35 USC 103(a) as being unpatentable over Parker '253 in view of Lepulu.

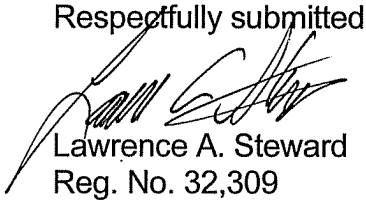
Claims 16-19 and 29 add additional details to the claims regarding the coil (claims 16-19) and the composition of the radiographic marker tube (claim 29). Each of these claims depends, directly or indirectly, from claim 1, and therefore

includes all of its limitations. Thus, these claims are not obvious in view of the citations for at least the same reasons that claim 1 is not obvious.

Conclusion:

Based on the foregoing, Applicants submit that the rejections to the claims have been overcome, and that all claims 1, 2, 4-6, 8-21, and 29 are in condition for allowance. Accordingly, Applicants respectfully request the timely issuance of a Notice of Allowance. If the Examiner has any further questions, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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